(12) UK Patent Application (19) GB (11) 2 209 947 (13) A

(43) Date of A publication 01.06.1989

(21) Application No 8822388.8

(22) Date of filing 23.09.1988

(30) Priority data
(31) 8722370 (32) 23.09.1987 (33) GB

(71) Applicants
Dr Subhash Chandra Halder
6 Heathlea, Well Head, Halifax, West Yorkshire, United Kingdom

John Glover Gill
38 Manor Heath Road, Halifax, West Yorkshire, HX3 0BE, United Kingdom

(72) Inventors
Dr Subhash Chandra Halder
John Glover Gill

(74) Agent and/or Address for Service
Appleyard Lees
15 Clare Road, Halifax, HX1 2HY, United Kingdom

(51) INT CL⁴
A61B 17/28

(52) UK CL (Edition J)
A5R RX4

(56) Documents cited
EP 0257118 A EP 0251583 A EP 0192840 A
DE 2854334 A US 3996931 A US 3433220 A

(58) Field of search
UK CL (Edition J) A5R RX4
INT CL⁴ A61B

(54) **Device for fixing femur fractures**

(57) A device for use in the treatment of fractures of the femoral neck, trochanteric and subtrochanteric regions of the femur incorporates a smoothly curved intramedullary rod 2 which can be introduced into the femoral shaft through the great trochanter 33, a hip screw 3 which can be introduced into the femoral neck 34 (through the outer cortex of the femur) through a fixing hole in the intramedullary rod and into the cancellous bone of the femoral neck and head; and a set screw 4 housed in the intramedullary rod to engage the hip screw. The set screw 4 may engage in one of a plurality of longitudinal grooves in the hip screw to allow limited axial movement of the hip screw through the hole in the intramedullary rod. The rod may be provided with a cloverleaf section to help prevent rotation relative to the femoral shaft. The device is suitable for both left- and right-handed femurs.

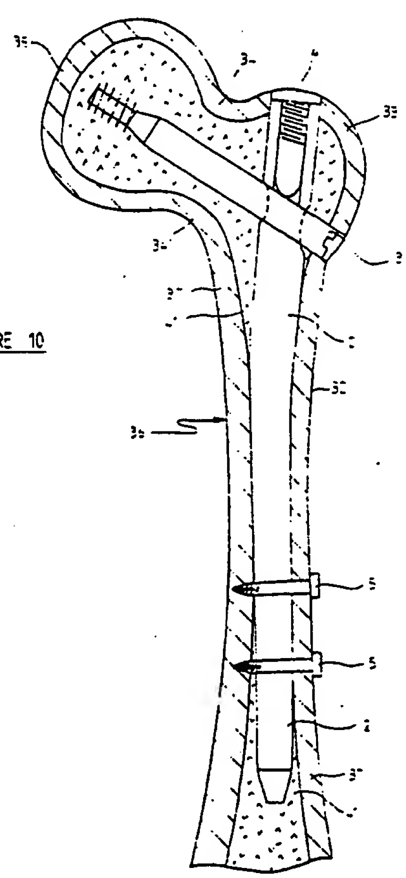


FIGURE 10

GB 2 209 947 A

1/4

2209947

FIGURE 1

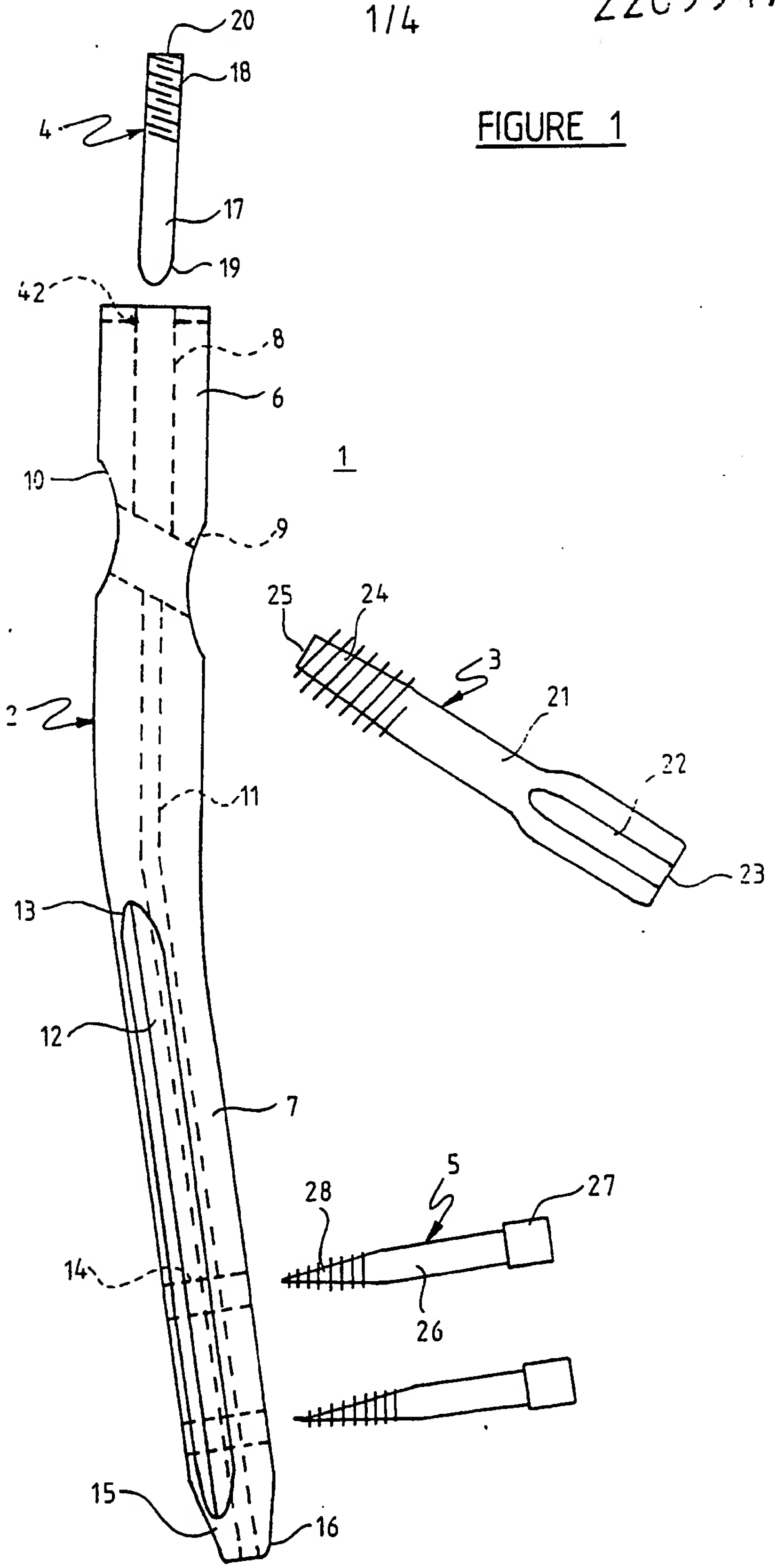
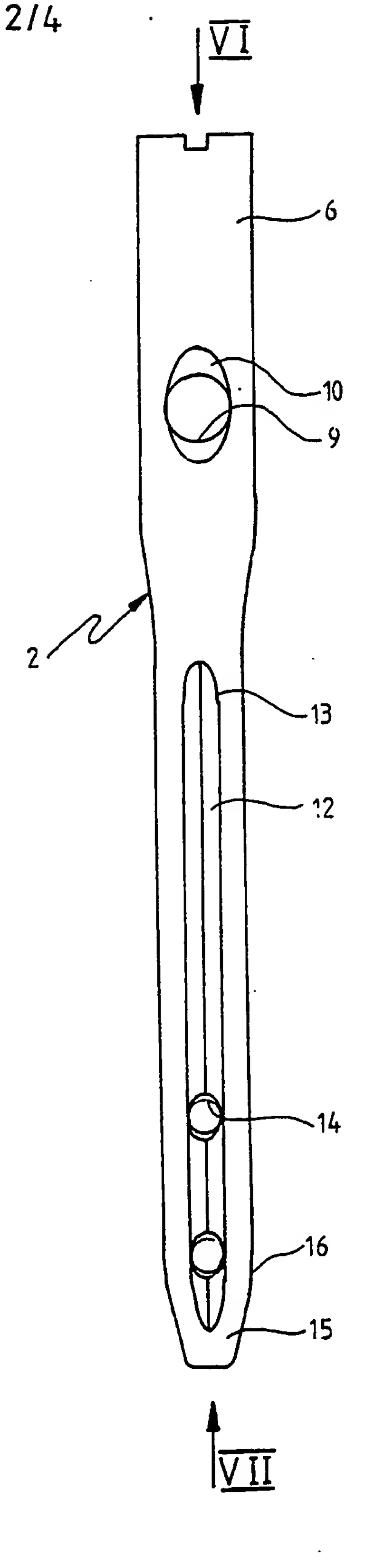


FIGURE 2



2209947

FIGURE 3

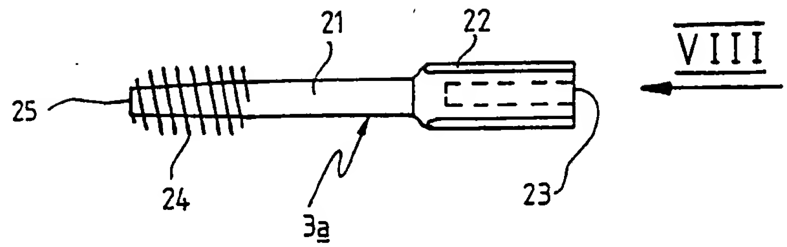


FIGURE 4

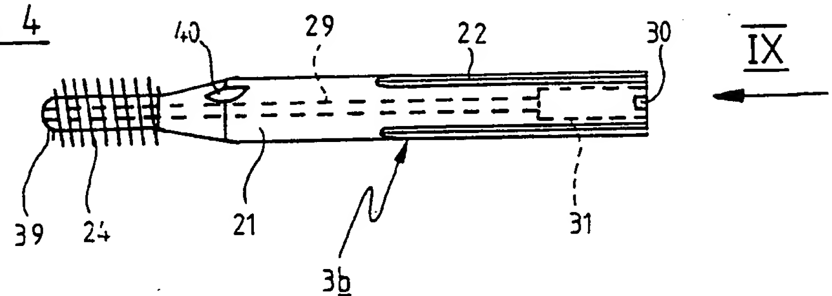


FIGURE 5

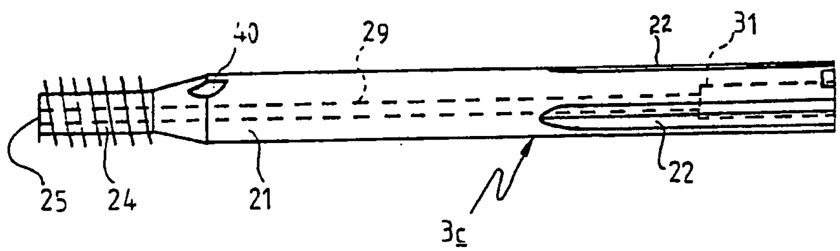


FIG. 6

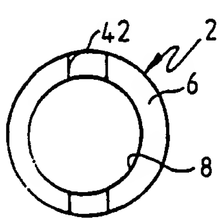


FIG. 7

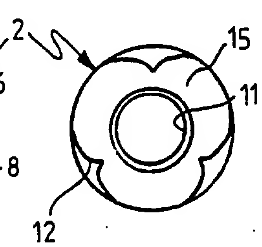


FIG. 8

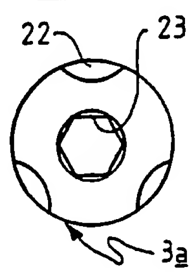
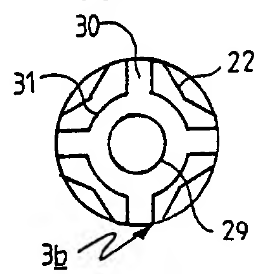


FIG. 9



2209947

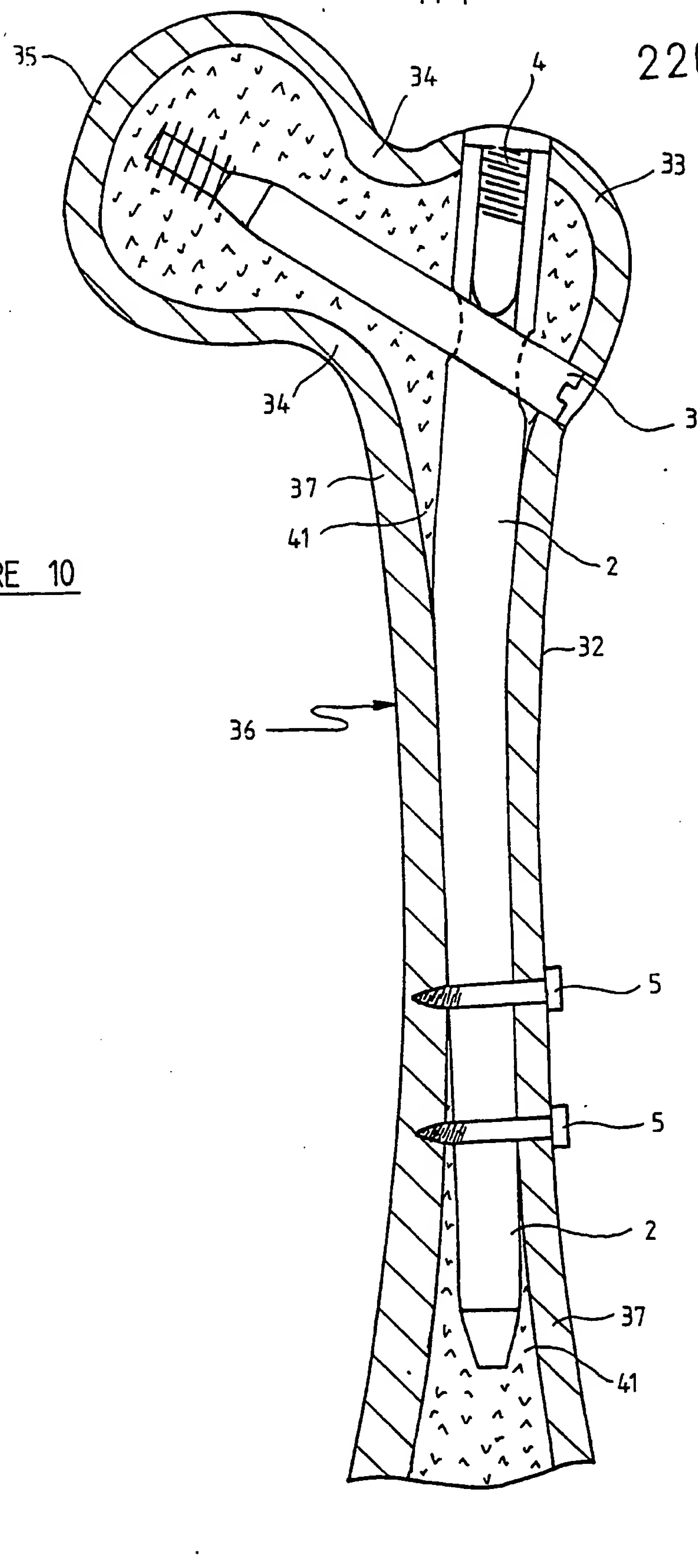


FIGURE 10

2209947

FIXATING DEVICE

This invention relates to a Fixating Device but more particularly to a device for the treatment of a femur fracture.

Devices for treating a femur fracture in the vicinity of the hip joint are known already in, for example, PCT Patent Publication Number 87/04612 in which a long anchoring arm is located partly within and partly outside the femur. The device described in PCT 87/04612 comprises generally two main parts which are formed integrally with one another, of which part one is provided with a guide hole for a fixation screw and is intended to lie outside the bore in a location near to the extension of the femur neck and part two has the form of a relatively long accurate anchoring arm which can be inserted through an insertion aperture in the bone wall so that it can be moved to an anchoring position within the femur in which the anchoring arm is supported by two mutually opposing walls within the femur.

In addition, devices for the fixation of fractures of the femur in the vicinity of the hip joint, which are at the present time in general use, have in common that a metal plate is fixed to the outer surface of the shaft of the femur by means of screws. The upper portion of the plate is fixed to the femur by means of a nail or one or more screws passing through the neck of the femur and into the head thereof.

These devices provide initial fixation of the fracture but in instances where the bone has been broken into more than two fragments, the device may fail to hold the fragments while union of the fracture is taking place

by natural process over the next three months or so. The plate may also be of insufficient strength and may bend or break. In addition the screws holding the plate to the femoral shaft may pull out.

A further disadvantage of such devices is that to affix the plate to the outer surface of the bone it is necessary for the surgeon to make an incision at least five inches in length and sometimes more and to cut through muscle causing additional pain post-operatively to the patient and often liberating the fracture haematoma the preservation of which is helpful to union of the fracture.

It will be appreciated that the patient may have sustained already a number of wounds in the vicinity of the femur and/or hip and the necessity of cutting an additional five inch (13 cm) incision will aggravate severely any post-operative discomfort suffered by the patient.

Devices of the type described above suffer from the disadvantage that they are supported by and fixed to the femur at only three small points ("three-point fixation") which induces a high degree of stress in the location of the contact points which can, in time, lead to further femur fractures and/or other damage.

A further disadvantage with at least some prior art devices is that it is necessary to use a heavy hammer or mallet to force them through an insertion aperture in the bone wall so that the first (exterior) portion of the fixating device lies flush with the outside of the bone. Apart from such a method prolonging the operation time, the action of applying heavy hammer blows to the end of

the fixating device can cause further serious fractures of the bone.

Another disadvantage of certain prior art devices is that they must be manufactured to fit either the left-hand femur or the right-hand femur which, in consequence, increases the production cost of each fixating device.

It is an object of the present invention to provide a fixating device for use in the treatment of a femur fracture which, at least, does not suffer from the serious disadvantages of the prior art.

According to the present invention a fixating device, for use in the treatment of fractures of the femoral neck, trochanteric and subtrochanteric regions, comprises:

a smoothly curved intramedullary rod which can be introduced into the interior of the proximal half (at least) of the femoral shaft through a small aperture formed through the tip of the great trochanter so that, in use, the rod is a close fit with the internal geometry of the femoral shaft;

an extended hip-screw which can be introduced into the femoral neck, through an aperture formed through the outer cortex (at least) of the femur, through a fixing hole formed through an upper portion of the intramedullary rod and into the cancellous bone of the femoral neck and femoral head, so that it maintains substantially close contact with the bone along the length of the screw not contained within the intramedullary rod; and,

an adjustable locking means which can act to lock the extended hip screw to the intramedullary rod.

The following important and innovative features of the present invention are pointed out:

1. a device with a curved rod closely fitting the internal geometry of the upper femoral shaft which can be inserted into the medullary cavity of the intact femur making it suitable for the treatment of all fractures which may be encountered in the neck, trochanteric or subtrochanteric regions of the femur;

2. a device including a rod of superior strength, which with stands the forces of body weight without bending or breaking;

3. a device with a longitudinally slotted hip screw, which permits operative compression of the fracture and holds this compression yet allows sliding as further compression of the fracture occurs under the forces of weight - bearing; and,

4. a device which can be inserted through two small incisions which do not cut muscle significantly nor disburb the fracture haematoma.

The intramedullary rod preferably comprises a generally cylindrical upper proximal portion, and a lower distal portion, having a rotation resistant generally cloverleaf-like cross section, there being an angle of between approximately 10 and 14 degrees between the axis of the proximal portion and the axis of the distal portion. The length of the proximal portion of the rod

is preferably approximately one-third of the total length of the rod.

The fixing hole formed, upwardly towards the hip, through the upper proximal portion of the rod may be cylindrical, and the axis of the hole is preferably at an angle of between approximately 125 and 145 degrees to the axis of the lower distal portion of the rod.

At least one location hole may be formed approximately horizontally through the lower portion of the rod, above a smooth part-conical distal end, each to receive a locking screw.

The hip screw preferably comprises a generally cylindrical shaft having a screw portion at its upper distal end and four equally spaced longitudinal grooves at its lower proximal end. In a preferred embodiment, the diameter of the hip screw is less than 1 mm smaller than the diameter of the fixing hole of the intramedullary rod.

The hip screw preferably has a substantially flat distal end so that any possibility of post-operative perforation of the cortex of the femoral head is minimized. The distal and of the hip screw preferable incorporates at least one bone-dust receiving recess.

The locking means may comprise a set screw, which can be located in a tapped hole formed coaxially through the proximal portion of the rod, so that an unthreaded rounded tip of the set screw can engage slideably with one of the grooves formed on the proximal end of the hip screw. In one embodiment, when the set screw is engaged with a groove of the hip screw, the head of the set screw

lies flush with the top of the intramedullary rod. In another preferred embodiment, the set screw is engageable with the proximal portion of the rod so that operative compression of the fracture is permissible.

In a preferred embodiment, the fixating device is suitable for use in either the left-hand or the right-hand femur.

One embodiment of the present invention will now be described, by way of example only, with reference to the accompanying drawings in which:-

Figure 1 is a front elevation of an unassembled device;

Figure 2 is a side elevation of an intramedullary rod of Figure 1;

Figure 3 is an elevation of a short hip screw of Figure 1;

Figure 4 is an elevation of a medium length hip screw of Figure 1;

Figure 5 is an elevation of long hip screw;

Figure 6 is a plan view in the direction of the arrow VI of Figure 2;

Figure 7 is a view in the direction of the arrow VII of Figure 2;

Figure 8 is a view in the direction of the arrow VIII of Figure 3;

Figure 9 is a view in the direction of the arrow IX of Figure 4; and,

Figure 10 is a somewhat diagrammatic cross-sectional front elevation of an assembled fixating device, in situ, within a femur.

In Figure 1, a Fixating Device 1 illustrated in an unassembled state, comprises generally on intramedullary rod 2, on extended hip screw 3, a set screw 4 and a pair of locking screws 5.

The intramedullary rod 2 comprises an upper cylindrical proximal portion 6, and lower cloverleaf-like sectional distal portion 7. The upper end of the proximal portion 6 has a threaded set screw receiving bore 8 formed downwardly through it and a rig-receiving slot 42. Towards the bottom of the proximal portion 6, the length of which is approximately 1/3 of the total length of the rod 2, is an upwardly inclined hip screw receiving hole 9 formed so that the hip screw 3 can be fixed through the hole 9 with a threaded part of a hip screw entering the hip bone. The edges of the inclined fixing hole 9 formed through the proximal portion 6 in the form of smoothly curved surfaces 10. In addition to the set screw receiving bore 8 the intramedullary rod 2 is, in this embodiment, provided with a narrow bore 11 formed through the lower part of the proximal portion of the rod and through the complete distal portion of the rod. The function of such narrow bore 11 is to minimise the use of materials and to provide a fixating device 1 which is as light as reasonably possible.

Three equally spaced elongated V-grooves 12 are formed along the exterior face of the distal portion 7 of the rod, as seen in Figures 1 and 7, so as to provide a cloverleaf-like cross section. As with the inclined fixing hole 9 the edges around the respective V-grooves 12 are formed with smoothly curved surfaces 13.

Towards the distal end of the rod 2 are located a pair of horizontal location holes 14 formed through the cloverleaf section 12. Again, the edges of the location holes 14 are formed with smoothly curved surfaces.

The distal end of the intramedullary rod 2 comprises a part conical section 15 having a smoothly rounded end 16.

In this, preferred, embodiment the axis of the upper proximal portion 6 over rod 2 is not coaxial with the axis of the lower distal portion 7 of the rod 2, but is at an angle of approximately 12 degrees to it. In other embodiments, this angle may be selected in the range 10 degrees to 14 degrees.

The intramedullary rod 2, in this case, is approximately 22 cm long and the diameter of the proximal end is approximately 17 mm. The maximum diameter of the cloverleaf section 7 is, in this case, approximately 13 mm although in other embodiments it may be chosen from any diameter in the range 11 mm to 15 mm. The minimum diameter is, in this case, approximately 10 mm although in other embodiments it could be greater or smaller. In Figure 1, the angle between the axis of the distal end of the rod 2 and the axis of the inclined fixing hole 9 is approximately 135 degrees, but in other embodiments the angle may be chosen from anywhere in the range 125

degrees to 145 degrees. Each of the horizontal location holes 14 has a diameter of approximately 6.5 mm and the two holes 14 are spaced apart by a distance of approximately 25 mm.

In Figure 3, a short hip screw 3a comprises a generally cylindrical solid shaft 21 having a screw portion 24 at its distal end and four equally spaced longitudinal grooves 22 at its proximal (lower) end (as seen in the drawings). The hip screw of Figure 3, is provided with a substantially flat distal end face 25 so that any possibility of post operative perforation of the cortex of the femoral head is minimized. In addition, in Figure 3, the proximal end of the hip screw 3a is provided with a hexagonal hole 23 formed through the end face thereof to receive an Allen key.

The hip screw 3 has a maximum diameter of approximately 11.5 mm and a length selected from 80 mm to 120 mm in increments of 5 mm.

In Figure 1, the set screw 4 comprises a solid shaft 17 which has a threaded upper end 18 and smoothly rounded lower end 19, therebeing a hexagonal hole 20 formed through the top face of the shaft 17 to receive an Allen key.

In use, the hip screw 3 is located within the inclined fixing hole 9 and the set screw 4 located within the threaded bore 8 so that the smoothly rounded lower end 19 of the set screw can be located within one groove 22 of the proximal end of the hip screw 3. In this manner, the fixating device 1 can be fitted to a patient with the hip screw located in the ideal position with respect to the fixing hole 9, though if the fracture

shortens the set screw will not prevent desirable sliding of the hip screw 3 in the fixing hole 9 of the rod 2.

Referring now to Figure 4, a hip screw 3b comprises a hollow shaft 21 which has a self tapping threaded distal end 24, having a rounded portion 39, and four equally spaced longitudinal grooves 22 at its proximal end. The hip screw 3b is also provided with a narrow longitudinal bore 29 passing from one end of the screw to the other end so as to save on materials and weight. In addition, the proximal end of the hip screw 3b includes two cruciate slots 30 and wide threaded bore 31. The arrangement of the cruciate slots 30 and the wide threaded bore 31 of the hip screw will be more clearly understood with reference to Figure 9 of the Drawings.

The long hip screw 3c of Figure 5 is substantially the same as the medium length hip screw of Figure 4 except, of course, it has an extended shaft portion 21 and a substantially flat distal and face 25 so that any possibility of post-operative perforation of the outer cortex of the femoral is minimized. At the present time, it is considered that the most effective hip screw is that illustrated in and described in connection with Figure 5, although the screws of Figures 3 and 4 are quite satisfactory.

In each of the hip screws 3b and 3c are formed three equally spaced part-circular bone-dust collecting recesses 40. Each recess is located towards the distal end of each screw in the locality of the screw portion 24.

Referring now to Figure 1, a pair of locking screws 5 each comprise a shaft portion 26, an enlarged head portion 27 and a self tapping threaded end 28. Although the diameter of each locking screw is approximately 6 mm the length will need to be chosen so that the head will project outside the shaft of the femur and the self tapping portion 28 will cut a path into the opposing wall of the femur.

In Figure 10, a femur 36 comprises a femoral shaft 32, at the top of which is located the great Trochanter 33 which leads into the femoral neck 34 and the substantially spherical femoral head 35. The femoral shaft 32 (at least) consists of a hard outer cortex 37 and a medullary canal 41.

To fit the fixating device 1 to a patient the following method is followed.

A drill is used to bore a hole through the great Trochanter 33 for a distance of from 22 cm to 24 cm or more. The upper 10 cm of the hole is drilled to a diameter of approximately 17 mm (if necessary by a non-flexible drill) and the lower 14 cm or so is drilled (by a flexible drill) to a diameter such that substantially all the soft cancellous bone of the medullary canal 41 of the femur is removed and the flexible drill encounters resistance against further drilling of the hard outer cortex 37. The intramedullary rod 2 is then passed through the hole formed through the great Trochanter 33 into the extended bore though the femoral shaft 32 until some resistance is encountered. At this point a portion of the upper proximal part of the rod 2 will be projecting from the great Trochanter 33. The intramedullary rod 2 may then be located substantially

correctly within the femur by means of gentle hammer or mallet blows applied to the proximal end of the rod 2.

The intramedullary rod 2 will be substantially correctly located when the axis of the inclined fixing hole 9 is approximately coaxial with the central part of the neck 34 of the femur. In other words, the intramedullary rod is inserted through the hole in the great Trochanter 33 until it is in a position where the hip screw 3 may pass through the fixing hole 9 in the rod and into the head 35 of the femur but without causing any unnecessary strain, weakening or damage to the neck of the femur.

When the intramedullary rod 2 is correctly positioned, the top face 6 thereof may be located above the great Trochanter 33 of a short patient or below the great Trochanter of a tall patient. A drilling rig (not shown) is attached to the threaded bone 8 of the proximal portion of the correctly positioned rod 2 so that further holes may be drilled, accurately, through other parts of the outer cortex of the femur. The drilling rig includes a guide so that a hole may be formed through an upper portion of the femoral shaft and into the femoral head 35 so that the extended hip screw 3 may be located therein passing though the inclined fixing hole 9 in the rod 2. In addition, the drilling rig also includes two guides so that a pair of holes may be drilled through both sides of a central part of the femoral shaft to receive the locking screws 5.

After the rod 2 has been inserted fully into the femur, a hole is drilled for the hip screw 3 by a double acting drill (ie. a drill which will excavate a hole having a first narrow diameter and a second wide

diameter) is used to drill a hole through the upper portion of the femoral shaft into the femoral head and in this case the wider part of the hole has a diameter of approximately the same as the diameter of the shaft of the hip screw and the narrower part of the hole has a diameter approximately the same as the diameter of the narrower part of the hip screw. The hip screw 3 is then pushed, by ordinary hand pressure, into the drill hole until resistance is encountered. A screwdriver, with a male tip designed to engage the female cruciate slots 30, is attached by means of the threaded bore 31 of the hip screw 3b or 3c and is used to rotate the proximal end of the hip screw so that the screw portion 24 thereof engages with a part of the inner cancellous bone of the femoral head 35. In the case of the hip screw 3a an Allen key is used in much the same manner. In either case, the hip screw 3 is rotated until the extreme proximal and lies a little short of the hard outer cortex of the femoral head 35. The fracture is then compressed without damaging or disturbing significantly the fractured haematoma by means of a tool which puts a traction force on the threaded end of the hip screw abutting with a sleeve placed temporarily on the outer cortex of the femoral shaft. The set screw 4 is then fed through the drilling rig until the rounded end 19 engages firmly with one of the grooves 22 of the hip screw 3.

As the hip screw 3b or 3c is being located in the receiving hole formed in the femoral neck and femoral head, bone dust, formed as a result of drilling the hole, collects in each of the bone dust collecting recesses 40, thus avoiding the problem of painfully compressing the interior of the head 35 of the femur.

At this point, any fracture of femur in the region of the femoral head, femoral neck or great Trochanter, will be satisfactorily treated. However, if there is a fracture across the femoral shaft 32 it will be possible that the lower part of the femoral shaft will rotate with respect to the upper part of the femoral shaft, notwithstanding the rotation resistant cloverleaf section of the distal part of the rod 2. In such a case, further holes are drilled through the femoral shaft to receive the locking screws 5 so that the head of the locking screws lie abutting the outer surface of the femoral shaft and the threaded portion of each screw engages a hole formed by the screw in the hard outer cortex of the femoral shaft.

Referring quickly to Figures 4 and 5 and, more particularly, to the four grooves 22 shown in each figure it is pointed out that those grooves may, in certain embodiments, be characterised in not having a constant depth.

In certain embodiments it is desirable to fix the bones in the region of the hip joint relatively rigidly, but not so rigidly that movement, however slight, is impossible. In those circumstances it may be desiable to allow some relative movement to take place to improve the healing process. Such movement may be permitted by forming each hip screw (3b or 3c as the case may be) with four grooves (as Figures 4 and 5 respectively) but, contrary to the drawings, with the depth of those grooves increasing generally gradually towards the threaded end (24). In this manner, each hip screw may slide more easily relative to the intramedullary rod by an amount at least sufficient to maximize the healing process. It is important to note that if some allowance of relative movement was not made,

the shrinkage of the bone in the region of the healing fracture haematoma would lead to possible further fractures of the bone or bones. In some cases total rigidity of a fixating device could lead to the distal end of the hip screw being forced through the femoral head .

The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification and/or drawings, or to any novel one, or any novel combination, of the steps of any method or process disclosed herein.

CLAIMS

1. A fixating device, for use in the treatment of fractures of the femoral neck, trochanteric and subtrochanteric regions, comprising:

a smoothly curved intramedullary rod which can be introduced into the interior of the proximal half (at least) of the femoral shaft through a small aperture formed through the tip of the great trochanter so that, in use, the rod is a close fit with the internal geometry of the femoral shaft;

an extended hip-screw which can be introduced into the femoral neck, through an aperture formed through the outer cortex (at least) of the femur, through a fixing hole formed through an upper portion of the intramedullary rod and into the cancellous bone of the femoral neck and femoral head, so that it maintains substantially close contact with the bone along the length of the screw not contained within the intramedullary rod; and,

an adjustable locking means which can act to lock the extended hip screw to the intramedullary rod.

2. A fixating device according to claim 1 wherein the intramedullary rod comprises a generally cylindrical upper proximal portion, and a lower distal portion, having a rotation resistant generally cloverleaf-like cross section.

3. A fixating device according to claim 2 wherein there is an angle of between approximately 10 and 14 degrees between the axis of the proximal portion and the axis of the distal portion.

4. A fixating device according to claims 2 or 3 wherein the length of the proximal portion of the rod is approximately one-third of the total length of the rod.

5. A fixating device according to any of claims 1 to 4 wherein the fixing hole is formed upwardly towards the hip through the upper proximal portion of the rod.

6. A fixating device according to claim 5 wherein the axis of the fixing hole is at an angle between approximately 125 and 145 degrees to the axis of the lower distal portion of the rod.

7. A fixating device according to any of claims 1 to 6 wherein the distal end of the intramedullary rod has a smooth part conical profile.

8. A fixating device according to any of claims 1 to 7 wherein at least one location hole is formed approximately horizontally through the lower portion of the rod.

9. A fixating device according to both claims 7 and 8 wherein the or each location hole is formed above the smooth part-conical distal end, each hole to receive a locating screw.

10. A fixating device according to any of claims 1 to 9 wherein the hip screw comprises a generally cylindrical shaft having a screw portion at its upper distal end and three or more equally spaced longitudinal grooves at its lower proximal end.

11. A fixating device according to claim 10 wherein the diameter of the hip screw is less than 1 mm smaller than the diameter of the fixing hole formed through the intramedullary rod.

12. A fixating device according to any of claims 1 to 11 wherein the hip screw has a substantially flat distal end so that any possibility of post-operative perforation of the cortex of the femoral head is minimized.

13. A fixating device according to any of claims 10 to 12 wherein the distal end of the hip screw incorporates at least one bone-dust receiving recess.

14. A fixating device according to claim 1 wherein the locking means comprises a set screw.

15. A fixating device according to claim 14 wherein the set screw can be located in a tapped hole formed coaxially through the proximal portion of the rod.

16. A fixating device according to claim 14 or 15 wherein an unthreaded rounded tip of the set screw can engage slideably with at least one of the grooves formed on the proximal end of the hip screw.

17. A fixating device according to any of claims 14 to 16 wherein when the set screw is engaged with a groove of the hip screw, the head of the set screw lies flush with the top of the intramedullary rod.

18. A fixating device according to any of claims 14 to 17 wherein the set screw is engageable with the proximal portion of the rod so that operative compression of the fracture is permissible.

19. A fixating device according to any of claims 1 to 18 wherein the slots of the hip screw generally increase in depth towards the threaded (distal) end of the hip screw.

20. A fixating device according to claim 19 wherein there are four equally angularly spaced slots.

21. A fixating device according to claims 19 or 20 wherein the longitudinally slotted hip screw permits operative compression of the fracture and holds this compression, but allows sliding as further compression of the fracture occurs under the forces of weight-bearing.

22. A fixating device according to any of claims 19 to 21 wherein the hip screw may slide with respect to the intramedullary rod in response to the healing process whereby the bone is shortened in the region of the fracture so that any danger of the distal end (at least) of the hip screw being pushed through the femoral head is minimized.

23. A fixating device according to any preceding claim wherein the fixating device is suitable for use in either the left-hand or the right-hand femur.

24. A fixating device according to any preceding claim wherein the device can be inserted into the bone structure through two small incisions which do not cut muscle significantly nor unreasonable disturb the fracture haematoma.

25. A fixating device substantially as hereinbefore described with reference to Figures 1 to 10 of the accompanying drawings.

Published 1988 at The Patent Office, State House, 66/71 High Holborn, London WC1R 4TP. Further copies may be obtained from The Patent Office, Sales Branch, St Mary Cray, Orpington, Kent BR5 3RD. Printed by Multiplex techniques ltd, St Mary Cray, Kent. Con. 1/87.